Title: **Role of Platelet Rich Plasma in supporting the recovery of post-partum Levator Ani Muscle trauma**

Running title: **Platelet rich plasma in levator ani muscle trauma**

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INFORMED CONSENT

(INFORMED CONSENT FORM)			
Principal researcher		: Dr Fernandi Moegni, MD, Urogynecologist	
Information giver		: Dr Fernandi Moegni & Team	
Information reciever Name Birth date & place Gender Address Phone number		: : : : :	
	INFORMATION TYPE	**CONTENT INFORMATION**	**SIGN**
1.	Study title	The role of Platelet Rich Plasma in supporting recovery of post-partum Levator Anal Muscle trauma	
2.	Study purpose	**General Purpose** To determine the benefits of PRP injection in repairing damaged pelvic floor muscles. **Specific Purpose** . To know the levator hiatal area assessed based on ultrasound images in patients given PRP injection compared to controls. . To know the improvement of pelvic floor muscle contraction strength assessed based on perineometric measurements in patients given PRP injection compared to controls.	
3.	Metodology	3.1 Study design This is a randomized control trial study 3.2 Place and Time	

		Public Health Center (Puskesmas) in Jakarta, Refferal Hospital (YPK Hospital, Budi Kemuliaan Hospital) in Jakarta. September 2016 until July 2019. 3.3 Study population All women who had vaginal delivery in Public Health Center (Puskesmas) in Jakarta and Refferal Hospital (YPK Hospital, Budi Kemuliaan Hospital) in Jakarta. All women must meet the inclusion criteria and pass the exclusion criteria 3.4 Inclusion criteria, exclusion criteria, drop out criteria 1.4.1 Inclusion criteria a. Primigravid women aged 20-35 years in the last trimester of pregnancy who are planning to give birth vaginally b. Willing to take part in this study c. Have a address and active phone number d. Sign the informed consent form to participate in study 1.4.2 Exclusion criteria a. History of pelvic floor muscle weakness before pregnancy b. History of pelvic surgery c. The patient has avulsion of the levator ani muscle on ultrasound examination d. Hemodynamically unstable e. Thrombocytopenia (platelets <150,000) f. Anemia (Hb < 10 g/dL) g. Sepsis h. Infection at the site of injury i. Use of oral corticosteroids in the last 2 weeks j. Smoke	

		k. Cancer, especially hematopoietic or bone l. Giving birth by cesarean section m. No perineoraphy after delivery 1.4.3 Drop out criteria a. Incomplete data from participant b. Participant not come at 40 days and 3 months post-partum assessment 3.5 Estimated Sample Size Total sample : 65 participants. 3.6 Sampling Method Consecutive sampling method. Participants were randomized to divide into two groups (intervention group and control group). 3.7 Study Flow • Submission of ethical clearance to the ethics committee. After obtaining approval from the ethics committee, socialization and preparation of research are carried out for doctors and nurses who work in the delivery room. • Provide a study form which contains identity information, phone number, inclusion criteria, exclusion criteria, and diagnosis. For delivery data such as delivery method, baby birth weight, duration of second stage of labor, degree of perineal tear, and clinical data of pelvic organ prolapse from phisical examination and pelvic floor ultrasound examination, perineometer. • Provide an informed consent form for participant • Periodic monitoring to evaluate the study protocol • The study form then combined with the participant's medical	

		record which will be filled out later by the researcher	
4.	Risk and Side effect	• Pain during phebotomy • Pain during injection • Potential allergic to PRP injection • Potential infection	
5.	Study and participant benefits	a. Provide a new alternative for pelvic floor muscle damage therapy, to prevent the progression of pelvic floor muscle damage which can lead to more complex medical problems b. Increase knowledge about the use of PRP to improve pelvic floor muscles and can be applied in medical practice c. Adding insight in the clinical field about the benefits of PRP on pelvic floor muscle repair	
6.	Study Procedure	Implementation a. All patients who come to Polyclinic in Public Health Center (Puskesmas) will be taken a history and physical examination to determine whether the patient meets the criteria or not b. Patients who met the criteria were provided with information about this study. Patients who are willing will be asked to fill out an informed consent. If the patient refuses to participate in this study, the reasons for refusal must be written. c. Randomization was performed and participant were divided into 2 groups (intervention group and control group). Participant will not know the results of randomization. Participant may know the results of randomization at the end of the study. d. Initial data collection on study form and approval to participate will be taken. Participants are required to write down their full name,	

		complete address, phone number, and family phone number. This is an attempt to increase the participation rate. e. Participant will be examined by ultrasound to assess pelvic floor biometry, perineometry to assess pelvic floor muscle strength. f. At delivery day, the participant in intervention group will be taken whole blood for preparation of 32 mL of PRP. After the PRP is ready, it will be injected directly into the levator ani muscle during post-partum perineorrhaphy. g. Participant in control group will still have whole blood taken for examination but no PRP preparation will be carried out. During perrineorrharphy will be injected lidocaine 1%. In this way, it is hoped that the participant will now know that she is in the intervention or control group. h. At 40 days and 3 months post-partum, the levator hiatal area was assessed using ultrasound examination and levator ani muscle strength was assessed by perineometry. The ultrasound operator does not know the patient group.	
7.	Potential discomfort	• Pain during phebotomy • Pain during injection • Potential allergic to PRP injection Potential infection	
8.	Confidentiality data	All patient data will be kept confidential and will only be used for study purposes	
9.	Compensation in case of side effects	Participants received the required treatment according to the hospital's procedure	
10.	Researcher name, phone number and address	Dr Fernandi Moegni, MD, Urogynecologist +62 82298111778	

11.	Participant number	63 participants	
12.	Potential damage	-	
13.	Research cost	42.652.400 IDR	
14.	Participant incentives	200.000,00 IDR	

January 15th, 2018

After recieved an explanation about the research that will be carried out by Dr. Fernandi Moegni, with the title: The role of Platelet Rich Plasma in supporting recovery of post-partum Levator Anal Muscle trauma. I have understood the information well.

By signing this form, I agree to participate in this research voluntarily without coercion from any party. If at any time I feel harmed in any form, I have the right to cancel this agreement.

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_____ _____

Participant's signature or thumb print Date

I have explained to the participant correctly and honestly about the purpose of the study, the benefits of the study, the study procedure, as well as the risks and potential incoveniences that may arise (detailed explanation according to what i mentioned above). I have also answered study-related questions.

_____ _____

Researcher's signature Date

_____

Researcher's name